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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,488	12/10/2003	Yaron Ilan	59046.000044	7675

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
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WASHINGTON, DC 20006-1109

EXAMINER

LE, EMILY M

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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02/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/733,488

Applicant(s)

ILAN ET AL.

Examiner

Emily Le

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-52 and 55-62 is/are pending in the application.
- 4a) Of the above claim(s) 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-52, 55-60 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/2007 has been entered.

Status of Claims

2. Claims 1-49 and 53-54 are cancelled. Claim 61 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/02/2005. Claims 50-52, 55-60 and 62 are under examination.

Claim Objections

3. Claim 56 is objected to because of the following informalities: the recitation "galatosyl ceramide" should be "galactosylceramide". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 50-52 and 55-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsuji et al.¹

The claims are directed to a method of modulating an immune response in a mammal with the administration of a glycolipid. Claim 51, which depends on claim 50, requires that the humoral, cellular or cytokine component of the immune system be modulated. Claim 52, which depends on claim 50, requires the modulation be specific or non specific. Claim 55, which depends on claim 50, limits the glycolipid to a monosaccharide ceramide. Claim 56, which depends on claim 55, limits the monosaccharide to glucosylceramide or galactosylceramide. Claim 57, which depends on claim 50, requires the administration method be intravenous, intra-muscular, subcutaneous, intra-peritoneal or oral.

Tsuji et al. teaches the administration of galactosylceramide to modulate the immune response in a mammal. [Entire PreGrant Patent Publication, claim 12, in particular.] Specifically, Tsuji et al. teaches that galactosylceramide is immunostimulatory, including the induction of a Th1 biased, cellular, including the production of cytokines, immune response. [Paragraph [0190], in particular.] The administration method used by Tsuji et al. includes intravenous, subcutaneous and intra-peritoneal. Tsuji et al. teaches the claimed composition. Hence, Tsuji et al. anticipates the claimed invention.

Regarding claims 58-60, which requires the immune response being modulated is part of the pathogenesis of an infection, including HCV; it should be noted that the because of the immunostimulatory nature of galactosylceramide, the administration of

¹ Tsuji et al. U.S. PreGrant Patent Publication No. 20030157135, filed July, 25, 2002.

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galactosylceramide would necessarily modulate the immune response in an individual, regardless of the type of disease the individual is diagnosed. Furthermore, Tsuji et al. also notes the administration of galactosylceramide to modulate the immune response that is part of HIV infection. [See claim 20, in particular.]

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 50 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al., as applied to claim 50.

Claim 62, which depends on claim 50, limits the mammal to a human.

Tsuji et al. did not administer galactosylceramide to a human. However, Tsuji et al. does suggest such administration to a human.

Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to administer galactosylceramide to a human. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to modulate the immune response in the human. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the immunostimulatory activity of galactosylceramide is known in the art.

Conclusion

8. No claims are allowed.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily M. Le/
Patent Examiner
Art Unit 1648

/E.L./